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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,593	01/10/2001	Michael G. Walker	PC-0025 CIP	9627
27904	7590	05/17/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/758,593	<b>Applicant(s)</b> WALKER, MICHAEL G.	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/22/2004 & 4/29/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3-11 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## RESPONSE TO AMENDMENT

### I. Status of Application, Amendments, and/or Claims

On further consideration and in view of Applicants' amendment after final, the finality of the rejection of the last Office action is withdrawn *AND PROSECUTION ON THE MERITS CONTINUES*. Applicants' amendment after final filed on April 29, 2004 has been entered in full.

Claims 1, 2, 6, 7, and 10-12 have been amended. Claims 1-12 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### II. Withdrawn Rejections

Applicants' amendment after final filed on April 29, 2004 has overcome all the rejections of claims 1 and 3-11 set forth in the record.

### III. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope of Enablement)

The rejection of claim 2 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph for scope of enablement, as set forth in Paper No. 20 and 22, is maintained.

At page 4 of the amendment after final filed on April 29, 2004, Applicants argue that claim 2 has been amended to recite specific fragments and variants of SEQ ID NO: 2, or the complements thereof, in "consisting of" language. This has been fully

*Never maintained*

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considered, but is not deemed to be persuasive because while the “consisting of” language is used in claim 2, part b) and part c), the preamble of the claim still recites the language of “comprising”, which is an open language. Thus, the claim encompasses a genus of cDNA comprising the fragments or variants of SEQ ID NO: 2. Since there is no functional limitation in the claim, one skilled in the art would not know how to make and use the claimed genus of cDNA. It is suggested that the preamble of claim 2 be amended to replace “comprising” with “consisting of”. Alternatively, if Applicants intend to claim the use of cDNA comprising a fragment of SEQ ID NO: 2 as a probe, they should amend claim 2, part b) and clearly indicate so and the binding target of the probe.

Claim 2, in part c), recites an isolated cDNA comprising a variant of SEQ ID NO: 2 consisting of SEQ ID NOS: 7-10 or the complements thereof. It is noted that even if the preamble of claim 2 were amended as suggested above by the Examiner, the specification would still not be found to enable one skilled in the art to use the cDNA consisting of a variant of SEQ ID NO: 2 (SEQ ID NOS: 7-10).

At the top of page 3, pages 4 to 5 of Applicants' Appeal Brief, Applicants argue that the claimed polynucleotides are useful in the diagnosis and treatment of muscle disorders such as muscle hypertrophy and clear cell sarcoma. Applicants argue that the skilled artisan would know how to use the claimed polynucleotides in hybridization assays to distinguish between Ankrd2V encoding polynucleotides and related molecules in a sample, in arrays to monitor large number of genes simultaneously and to identify

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genetic variants and mutations, and for chromosomal mapping without undue experimentation.

This has been fully considered, but is not deemed to be persuasive for the following reasons. First, claim 2, part c), recites a variant of SEQ ID NO: 2 selected from SEQ ID NO: 7-10. However, sequence analysis shows that SEQ ID NO: 7-10 only have 15.9%, 14.7%, 18.2%, and 13.6% match with SEQ ID NO: 2, <sup>with</sup> which best local similarity 82.7%, 81.3%, 82.9%, and 85%, respectively. Thus, SEQ ID NO: 7-10 only shares some similarity with a small portion of SEQ ID NO: 2. The instant disclosure asserts that these cDNAs are particularly useful for producing transgenic cell lines or organisms which model human disorders upon which potential therapeutic for such disorders may be tested (bottom of page 11 of specification). However, the specification is silent on how to use these variants of a small portion of SEQ ID NO: 2 to produce transgenic cell lines or organisms which model a human disorder, in particular human clear cell sarcoma. R

Secondly, while the fragments of SEQ ID NO: 2 may be used as a probe for the diagnosis of clear cell sarcoma, a variant of SEQ ID NO: 2 (SEQ ID NOS: 7-10) may not be used as a probe for the diagnosis of clear cell sarcoma, because such a cDNA comprising (or consisting of) a variant of SEQ ID NO: 2 may not specifically bind to the cDNA of SEQ ID NO: 2. Thus, one skilled in the art would not be able to practice the present invention without undue experimentation.

Finally, Applicants argument that the claimed polynucleotides can be used in hybridization assays, in arrays to monitor large number of genes simultaneously, for identifying genetic variants and mutations, and for chromosomal mapping is invalid

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because the specification has to enable the use of the claimed invention that satisfies the utility requirement under 35 U.S.C. §101, not just any research uses.

#### **IV. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Written Description)**

On further consideration, the rejection of claim 2 under 35 U.S.C. § 112, first paragraph (written description), as set forth in paper No. 20 is reinstalled.

Claim 2 is rejected because the claim uses an open language “comprising”, does not require that the cDNA possesses any particular biological activity, nor any particular disclosed distinguishing feature and the specification fails to provide an adequate written description and evidence of possession of such a claimed genus of cDNA.

It is suggested that the preamble of claim 2 be amended to replace “comprising” with “consisting of” to overcome this rejection.

#### **V. Claim Objection**

Claim 12 is objected to because there is a typographic error in line 2 of the claim, the word “and” should be inserted between “DNA molecules” and “RNA molecules”, not at the end of the claim.

Appropriate correction is required.

#### **VI. Conclusion**

Claims 1 and 3-11 are allowed.

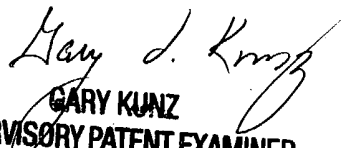
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. The fax number for this Group is (703) 872-9306.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li  
Examiner  
May 11, 2004

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**